K080936

MAY 12 2008

SECTION 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of the 510(k) pre-market notification for the ConforMIS Total Knee Repair System ("iTotal"): Tibial Component: Extension of Size Range is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Summary of Safety and Effectiveness

Submitted By: ConforMIS, Inc.
2 Fourth Avenue
Burlington, MA 01803

Contact Person: S. Michael Sharp, PhD
Sr. Vice President, Regulatory/Clinical & Quality

Date: March 24, 2008

Trade/Proprietary Name ConforMIS Total Knee Repair System (iTotal): Tibial Component Extended Thickness Range

Common Name Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

Reference/Classification Name: 21 CFR 888.3560 – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

Predicate Devices

Technological Characteristics	Design & Insert Thickness	Indications for Use
ConforMIS Total Knee Repair System (K052687)	ConforMIS Total Knee Repair System (K052687)	ConforMIS Total Knee Repair System (K052687)
ConforMIS BiCompartmental Knee Repair System (K053488)	ConforMIS BiCompartmental Knee Repair System Polyethylene Tibial Insert (K072368)	ConforMIS BiCompartmental Knee Repair System (K053488)

Intended Use:

The ConforMIS Total Knee Repair System ("iTotal") is a minimally invasive, bone preserving primary total knee system intended 'for use in patients with severe knee joint pain and disability. The indications for use include restoring joint function and relief of pain due to:

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid
- arthritis of the knee
- Post traumatic loss of joint function
- Mild to moderate valgus or varus deformity of the knee

The ConforMIS Total Knee Repair System (iTotal): Tibial Component: is intended only for use with bone cement.

Device Description: The additional 6.0 mm thickness option for the ConforMIS Total Knee Repair System tibial component is intended to provide the surgeon with an additional option for sizing the tibial component. The X/Y dimensions of the component (i.e. the two-dimensional shape or "footprint") are designed to conform to the patient's anatomy as closely as possible based on images (MRI or CT scan) of the patient's knee. It is available as an UHMEPE component with minimal thickness of 6.0 mm.

Comparison to Predicates: The ConforMIS Total Knee Repair System tibial component in the additional size Component is substantially equivalent to the tibial components cleared for use with the ConforMIS uni-compartmental ("iUni") and bi-compartmental ("iDuo") Device in terms of absolute minimum thickness. It is equivalent to the ConforMIS Total Knee Repair System in the use of imaging data to design patient-matched implant geometry; in terms of design and production process; in the use of identical materials and indications. It is substantially equivalent to the cited predicate devices in terms of design, materials, mechanical safety and intended use. All are intended for cemented use only.

Performance Data

Non-clinical Performance and Conclusions:
Testing completed as part of the design verification procedure for the ConforMIS Total Knee Repair System Tibial component found this device to be as safe and effective as the predicate devices, further confirming substantial equivalence.

Clinical Performance:
Clinical data and conclusions are not necessary to demonstrate substantial equivalence.

SUMMARY

Based on the similarities in design, materials, function and intended use the ConforMIS Total Knee Repair System (iTotal*):* Tibial Component 6.0mm is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. In addition, the ConforMIS Total Knee Repair System ("iTotal") 6 mm Tibial Component raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ConforMIS, Inc.
% S. Michael Sharp, PhD
Senior Vice President
Regulatory and Clinical Affairs
2 Fourth Avenue
Burlington, Massachusetts 01803

MAY 12 2008

Re: K080936
Trade/Device Name: ConforMIS Total Knee Repair System Tibial Component: 6.0 mm Thickness
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: March 31, 2008
Received: April 2, 2008

Dear Dr. Sharp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): ~~#K0080936~~ K080936

Device Name: ConforMIS Total Knee Repair System

Indications for Use:
The ConforMIS Total Knee Repair System ("iTotal") is a minimally invasive, bone preserving primary total knee system intended 'for use in patients with severe knee joint pain and disability. The indications for use include restoring joint function and relief of pain due to:

Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis of the knee

Post traumatic loss of joint function

Mild to moderate valgus or varus deformity of the knee

The ConforMIS Total Knee Repair System ("iTotal") is intended only for use with bone cement.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Neil R Ogden for m x m

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080936